DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Cincinnati District Office
6751 Steger Dr.
Cincinnati, OH 45237
Telephone: (513) 679-2700
FAX: (513) 679-2771

Via Federal Express

WARNING LETTER CIN-08-36320-16

May 21, 2008

James R. Overman
Precision Herbs, L.L.C.
9804 Township Road 89
Killbuck, OH 44637

and

Overman's Healthy Choices, Inc.
9227 Township Road 82
Millersburg, OH 44654

Dear Mr. Overman:

This letter concerns your firm's marketing of the products Activase, Amorph, Apritum, CanAlk, CancerGene, Carcinogex, Fungustum, Molex, Neoplasmex, Pau d Arco Bark, ThermaPop, TNF-Max, TumGo, Tumorex and VX-O. According to information on your website, www.precisionherbs.com, these products are intended to prevent, treat, or cure disease conditions or to affect the structure or function of the body.

We note that you have attempted to disclaim some of the statements on your site that indicate that the products are intended to prevent, treat, or cure disease conditions or to affect the structure or function of the body. For example, your site says regarding your products:

> "Disclaimer: This information is for educational purposes only and is not recommended as a means of diagnosing or treating an illness. All matters concerning physical or mental health should be supervised by a health practitioner knowledgeable in treating that particular condition. The authors of this website neither directly nor indirectly dispense medical advice; nor do they prescribe any remedies or assume any responsibility for those who choose to treat themselves."

However, untrue or misleading information in one part of your site will not be mitigated by inclusion of such a "disclaimer." [21 C.F.R. 202.1(e)(3)(i)]

Statements on your website that document the intended uses of these products include, but are not limited to, the following:

Activase

- *"Historically used to help activate the immune system to attack tumors, to aid other tumor-dissolving herbal products, and to dissolve the protective protein coating from the surface of tumors so the body can attack them."*

Amorph

- *"Historically used with tumor shrinking combinations to keep tumors from morphing from one type to another."*

Apritum

- *"Historically used to help dissolve some malignant tumors caused by slime molds."*

CanAlk

- *"Historically used 1 hour after meals to alkalize and help dissolve malignant tumors. This is a TGF-beta inhibitor and can be used to prevent the reoccurence [sic] of malignant tumors.*

CancerGene

- *"Historically used to help switch on all three genes that inhibit cancer."*

Carcinogex

- *"Historically used to help remove carcinogenic toxins. Helps remove some kinds of tumors when used with tumor shrinking herbs."*

Fungustum

- *"Historically used to help dissolve malignant tumors caused by fungus infection."*

Molex Salve

- *"Historically used to help kill mildews in the skin and dissolve some kinds of skin cancers."*

Neoplasmex

- *"Historically used to help prevent the formation of new abnormal cells in normal tissue and inside tumors."*

Pau d Arco Bark

- *"Historically used to purify the blood, fight fungal infection and dissolve fluke induced tumors."*

ThermaPop

- *"Historically used with a hot water bottle to break open malignant cells when exposed to heat. Take 1 teaspoon and hold a hot water bottle over the tumor area for 20 minutes."*

TNF-Max

- *"Historically used to help improve immunity by increasing the tumor necrosis factor. Helps dissolve some tumors when used with tumor-dissolving combinations."*

TumGo

- *"Historically used to help shink [sic] certain types of malignant tumors after killing parasitic flukes."*

Tumorex

- *"Historically used to help shrink some types of tumors. This works for dissolving slime mold tumors only after killing the slime mold living inside the tumor."*

VX-O

- *"Historically used to help dissolve fibroid tumors and dissolve fibrous material in the breast."*

Activase, Amorph, Apritum, CanAlk, CancerGene, Carcinogex, Fungustum, Molex, Neoplasmex, Pau d Arco Bark, ThermaPop, TNF-Max, TumGo, Tumorex and VX-O are drugs, as defined by section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(g)(1), because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals. Moreover, these are new drugs, as defined by section 201(p) of the Act, 21 U.S.C. § 321(p), because they are not generally recognized as safe and effective for their labeled uses. Under section 301(d) and 505(a) of the Act, 21 U.S.C. §§ 331(d) and 355(a), a new drug may not be introduced or delivered for introduction into interstate commerce unless an FDA-approved application is in effect for it. Your sale of the aforementioned products without approved applications violates these provisions of the Act.

Furthermore, since Activase, Amorph, Apritum, CanAlk, CancerGene, Carcinogex, Fungustum, Molex, Neoplasmex, Pau d Arco Bark, ThermaPop, TNF-Max, TumGo, Tumorex and VX-O are offered for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners, adequate directions cannot be written so that a layman can use the products safely for their intended uses. Thus, your products' labeling fails to bear adequate directions for their intended uses, causing them to be misbranded under section 502(f)(1) of the Act, 21 U.S.C. § 352(f)(1).

The issues and violations cited in this letter are not intended to be an all-inclusive statement of violations that exist in connection with your products. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility to assure that your firm complies with all requirements of federal law

and FDA regulations. We advise you to review your websites, product labels, and other labeling and promotional materials for your products to ensure that the claims you make for your products do not cause them to violate the Act.

You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and injunction. Other federal agencies may take this Warning Letter into account when considering the award of contracts.

Within fifteen working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to correct violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the correction. If you no longer manufacture or market the aforementioned products, your response should so indicate, including the reasons that, and the date on which, you ceased production. Additionally, if another firm manufactures the products identified above, your reply should include the name and address of the manufacturer. If the firm from which you receive the products is not the manufacturer, please include the name of your supplier in addition to the manufacturer.

Please direct your response to the U.S. Food and Drug Administration, 6751 Steger Dr., Cincinnati, OH 45237-3097, Attention: Karen Gale Sego, Compliance Officer.

A description of the new drug approval process can be found on FDA's internet website at http://www.fda.gov/cder/regulatory/applications/default.htm. Any questions you may have regarding this process should be directed to the Food and Drug Administration, Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, 10903 New Hampshire Ave., WO51-2201, Silver Spring, MD 20993.

Sincerely,

Carol A. Heppe
Cincinnati District Director

cc: Charles Kirchner, Chief, Food Safety Division
Ohio Department of Agriculture
8995 East Main Street
Reynoldsburg, OH 43068-3399